

## **REMARKS/ARGUMENTS**

Reconsideration of this Application is respectfully requested. Claims 1, 3-6, and 8-25 are pending in the present Application. In the Office Action dated November 10, 2010, the Examiner rejected pending claims 1, 3-6, and 8-25 on various grounds. In view of the following remarks, favorable consideration and allowance of the Application is respectfully requested.

### **35 U.S.C. §103 Rejections**

Obviousness is a question of law, based on the factual inquiries of 1) determining the scope and content of the prior art; 2) ascertaining the differences between the claimed invention and the prior art; and 3) resolving the level of ordinary skill in the pertinent art. *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. *In re Royka*, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). *See* MPEP 2143.03. The Applicant respectfully asserts that the cited references fail to teach or suggest all the claim limitations.

- A. Claims 1, 3-6, and 8-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Pat. No. 6,616,765 to Castro, *et al.* (the *Castro* patent) in view of U.S. Patent No. 5,873,904 to Ragheb, *et al.* (the *Ragheb* patent).**

The Applicant respectfully asserts that the *Castro* patent and the *Ragheb* patent, alone or in combination, fail to teach or suggest all the claim limitations.

The *Castro* patent and the *Ragheb* patent fail to disclose, teach, or suggest:

a stent delivery system including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first

coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer; wherein: the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 1; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; and a coating including a first coating section comprising a first polymer and a second coating section comprising a second polymer, the first polymer being different than the second polymer; wherein: the first coating section is a single layer directly adjacent to and completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; and the second coating section is another single layer directly adjacent to and completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments; and the first region and the second region are discrete, and the first coating section and the second coating section are discrete, as recited in independent claim 6; or

a method for producing a coated stent including providing a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair

of longitudinally adjacent cylindrical stent segments; mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 11;

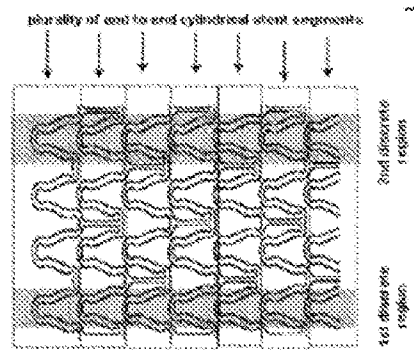
a system for producing a coated stent from a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments, including: means for mixing a first polymer and first therapeutic agent with a first solvent to form a first polymer solution; means for applying the first polymer solution directly to the stent in the first region to form a first coating section of a coating completely covering the outer surface in the first region of the longitudinally adjacent cylindrical stent segments; means for mixing a second polymer and second therapeutic agent with a second solvent to form a second polymer solution; and means for applying the second polymer solution directly to the stent in the second region to form a second coating section of the coating completely covering the outer surface in the second region of the longitudinally adjacent cylindrical stent segments, wherein the first coating section and the second coating section are

discrete, and the first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 18; or

a coated stent including a stent having a plurality of end-to-end cylindrical stent segments, the axes of the plurality of cylindrical stent segments lying along a longitudinal axis of the stent, the stent having a discrete first region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and a discrete second region continuous across at least one pair of the longitudinally adjacent cylindrical stent segments; a first polymer including a first therapeutic agent, the first polymer being adjacent to and completely covering the outer surface in the discrete first region of the longitudinally adjacent cylindrical stent segments as a first coating section of a coating; and a second polymer including a second therapeutic agent, the second polymer being adjacent to and completely covering the outer surface in the discrete second region of the longitudinally adjacent cylindrical stent segments as a second coating section of the coating, the first polymer being different than the second polymer, wherein the first coating section and the second coating section are discrete, and the discrete first region has a longitudinal length greater than the diameter of the stent in an expanded state, as recited in independent claim 22.

At most, the *Castro* patent discloses a patterned coating on a prosthesis, for example a stent, and a method for forming the coating, plus an apparatus for forming the patterned coating. *See* Abstract. Composition 10 may be applied along struts 68 of prosthesis 12 in a variety of deposition patterns and having a variety of thicknesses. *See* Figures 7A-15D; column 15, line 34 - column 19, line 18.

On pages 2 and 3 of the Office Action dated November 10, 2010, the Examiner presented one particular pattern as seen below and asserted that the choosing of regions is subjective and not limited by the claims. The Applicant respectfully disagrees.



Assuming *arguendo* the pattern posited would be one which satisfies the Applicant's claims, the pattern is not disclosed in the *Castro* patent. The *Castro* patent discloses a patterned coating on a prosthesis, but fails to disclose the pattern extending over regions as claimed. The regions are limited in the claims so that the discrete first region is continuous across at least one pair of the longitudinally adjacent cylindrical stent segments and the discrete second region is continuous across at least one pair of the longitudinally adjacent cylindrical stent segments. Further, the *Castro* patent fails to disclose discrete coating sections over the regions.

At most, the *Ragheb* patent discloses that the bioactive material may be posited on the one surface of structure 12 in a specific geometric pattern. For example, the tips or arms of a stent may be free of bioactive material, or the bioactive material may be applied in parallel lines, particularly where two or more bioactive materials are applied to the same surface. *See* column 19, line 64 - column 20, line 3. This is the sole and complete disclosure of the *Ragheb* patent regarding geometric patterns.

On page 3 of the Office Action dated November 10, 2010, the Examiner asserted that the *Ragheb* patent discloses the concept of applying coatings in different patterns. The Applicant respectfully notes that the disclosure of the *Ragheb* patent regarding geometric patterns is limited to those few features discussed in the previous paragraph and that the combination of the *Castro* patent and the *Ragheb* patent would not suggest the Applicant's invention as claimed to one skilled in the art.

In the Response to Arguments on page 7 of the Office Action dated November 10, 2010, the Examiner noted that one cannot show nonobviousness by

attacking references individually. The Applicant respectfully submits that all the claim limitations must be taught or suggested by the prior art for a showing of obviousness: as discussed above, the *Castro* patent and the *Ragheb* patent, alone or in combination, fail to do so. The scope and content of the prior art must be determined in order to examine differences between the prior art and the claims at issue under a *Graham* analysis for obviousness.

Claims 3-5; claims 8-10; claims 12-17; claims 19-21; and claims 23-25 depend directly or indirectly from independent claims 1, 6, 11, 18, and 22, respectively, and so include all the elements and limitations of their respective independent claims. The Applicant therefore submits that the dependent claims are allowable over the *Castro* patent and the *Ragheb* patent for at least the same reasons as set forth above with respect to their independent claims.

Withdrawal of the rejection of claims 1, 3-6, and 8-25 under 35 U.S.C. §103(a) as being unpatentable over the *Castro* patent and the *Ragheb* patent is respectfully requested.

### **Conclusion**

For the foregoing reasons, Applicant believes all the pending claims are in condition for allowance and should be passed to issue. The Commissioner is hereby authorized to charge any additional fees which may be required under 37 C.F.R. 1.17, or credit any overpayment, to Deposit Account No. 01-2525. If the Examiner feels that a telephone conference would in any way expedite the prosecution of the application, please do not hesitate to call the undersigned at telephone (707) 543-0221.

Respectfully submitted,

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